DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

June 19, 2001

WARNING LETTER
CHI-37-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William Morris, President
X-Cel X-Ray Corporation
4220 Waller Drive
P.O. Box 1857
Crystal Lake, IL 60039-1857

Dear Mr. Morris:

During an inspection of your firm, located in Crystal Lake, IL, from December 6 to December 7, 2000, Investigator Chad Schmear determined that your firm manufactures X-ray systems. X-ray systems are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Failure of management with executive responsibility to establish its policy and objectives for, and commitment to, quality. For example, your firm lacks a formal quality policy.

2. Failure to establish a quality plan that defines the quality practices, resources, and activities relevant to the devices that your firm designs and manufactures.

3. Failure to establish procedures for quality audits.

4. Failure to establish procedures to control the design of your devices in order to ensure that specified design requirements are met.

5. Failure to establish procedures for implementing corrective and preventive action including requirements for investigating the cause of nonconformities relating to product processes and the quality system.

Additionally, the above stated inspection revealed that your devices are misbranded within the meaning of Section 502(t)(2) of the Act, in that your firm failed to establish medical device reporting procedures as required by the Medical Device Reporting (MDR) regulation, as specified in 21 CFR, Part 803.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

We request that you take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 30 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Michael Lang, Compliance Officer, at the above address.

Sincerely,

\s\
Raymond V. Mlecko
District Director